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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,488	01/22/2002	Mark E. Johnson	G&C 126.4-US-U1	4738

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EXAMINER	
HUFF, SHEELA JITENDRA	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,488	JOHNSON ET AL.	
	Examiner	Art Unit	
	Sheela J Huff	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____.

DETAILED ACTION

Claims 1-29 are pending.

Priority

The pending claims have priority to the provisional application, filed 1/19/01.

Information Disclosure Statement

The IDS filed 9/3/02 and 11/25/02 have been considered and an initialed copy of the PTO-1449s are enclosed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-11, 21-23 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Newman et al CA 129:280894 (reference found in Ids filed 11/25/02).

This reference discloses the immunization of mice with poly(d,l-lactic-co-glycolic acid) (PLGA also known as PLG) microspheres containing a MUC1 peptide (the peptide corresponds to the variable tandem repeat domain and this reads on applicant's SEQ ID NO. 1). The reference further discloses the use of an immunomodulator (adjuvant) MPLA in combination with the microspheres.

It is an inherent property of the microspheres that they are present in the sizes claims in claims 9-11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newman et al CA 129:280894 in view of Tice et al US 5407609 and applicant's admission on page 8, lines 16+ of the specification.

The Newman reference has been discussed above.

The only differences between the instant invention and the reference is that the reference does not disclose a method of encapsulation or the other types of adjuvants of claim 8.

Tice et al disclose a method of microencapsulating "an agent to from a microencapsulated product having the steps of dispersing an effective amount of the agent in a solvent containing a dissolved wall forming material to form a dispersion" (reads on steps (a) and (b) of claim 12), "combining the dispersion with an effective amount of a continuous process medium to form an emulsion that contains the process medium and microdroplets having the agent" (reads on steps (c) and (d) of claim 12), "the solvent and the wall forming material and adding rapidly the emulsion to an effective amount of a extraction medium to extract the solvent from the microdroplets to form the microencapsulated product"(reads on step (e) of claim 12) (abstract). The reference goes on to mention a multitude of agents which can be encapsulated by the method (see col. 4-5). Mucin is not mentioned.

On page 8 of the specification, applicant admits that the adjuvants of claims 8, 16 and 24 are known in the art.

In view of Tice et al, which discloses a method of microencapsulating an agent and in view of the fact that Tice et al discloses a multitude of agents which can under

this process, it would have been obvious to one of ordinary skill in the art at the time of the invention to microencapsulate mucin using the Tice et al method to produce the microsphere of Newman et . The use of any known adjuvant is within the purview of one skilled in the art in view of applicant's admission.

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newman et al CA 129:280894 in view of Tice et al US 5407609, applicant's admission on page 8, lines 16+ of the specification Eldridge et al Molecular Immunology vol. 28 p. 287 (1991) and Finn et al US 5827666.

Newman et al and Tice et al have been discussed above.

The only different between the instant invention and the reference is the formation of a vaccine and the use of vaccine to treat tumor growth, prolong survival and treating or preventing cancer.

Eldridge et al discloses the use of microspheres in a vaccine delivery system and the delivery system contains microspheres with PLG.

Finn et al disclose the use of a mucin peptide containing tandem repeats (col. 5, lines 48-50) to inhibit the growth of cancer cells (col. 6, lines 40+0 and producing immunity (ie prolonging survival) to a disease, such as cancer (col. 7, lines 25+).

Thus, in view of the teachings in Eldridge et al and Finn et al, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to use the microspheres of Newman et al, produced by the method of Tice et al, in a vaccine composition to inhibit the growth of cancer cells. The motivation comes from the fact

that the mucin is known to inhibit cancer growth and that it is available in microsphere form and that such forms are known to be used in vaccines.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheela J. Huff

Sheela J Huff
Primary Examiner
Art Unit 1642

sjh